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EXAMINER

LEWIS, PATRICK T

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 08/26/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,384

Applicant(s)

HOVINEN ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group IV wherein the species elected is compound 37 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the restriction requirement improperly divides claim 1 into 6 different groups. This is not found persuasive because 35 U.S.C. 121 states that the Commissioner may require restriction if two or more "independent and distinct" inventions are claimed in one application. It matters not whether said inventions are presented in a single or multiple claims. Applicant cannot escape a restriction requirement merely by placing plural patentably distinct inventions in a single claim. *In re Weber* is noted. The examiner does not refuse to exam the claim(s), but rather, the examiner has restricted the examination to a single invention within a claim. Of course if there is any generic linking concept that links all the inventions together, the office will examine that linking concept at the same time as the elected invention. In the instant case there is no generic linking concept between the restricted inventions. While the Office has been cautious in restricting within a single claim, it is done so under the authority of *In re Hamish* 206 USPQ 300, 305 CCPA. *In re Hamish* indicates that restriction would not be proper within a single claim when the claimed embodiments share a common utility and a common structure feature disclosed to be essential for that utility. Applying this test in this case, the claimed embodiments have a common utility but lack a common structural feature disclosed to be essential to that utility. In conclusion, restriction in the instant

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application is proper under *In re Hamish*. Though examination in this application is restricted to a single invention, the entire scope of the instant claim can be made subject to examination upon filing of an appropriate number of divisional applications.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 12-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, *In re Glass*, 181 USPQ 31; 492 F.2d 1228 (CCPA 1974).

A written description analysis involves three principle factors:

1. Field of the invention and predictability of the art
2. Breadth of the claims
3. For each claimed species/genus, possession of claimed invention at the time of the filing.

The instant specification is drawn to a labeling reactant of formula (I). Each of the variables **A**, **E**, and **E'** drawn to a linker arm, which is formed of one to ten moieties, each moiety being selected from a group consisting of phenylene, alkylene containing 1-12 carbon atoms, ethynediyl ($-C\equiv C-$), ether ($-O-$), thioether ($-S-$), amide ($-CO-NH-$, $-NH-CO-$, $-CO-NR'-$ and $-NR'-CO-$), carbonyl ($-CO-$), ester ($-COO-$ and $-OOC-$), disulfide ($-S-S-$), diaza ($-N=N-$), and tertiary amine ($-N-R'$), wherein R' represents an alkyl containing less than 5 carbon atoms lacks support wherein applicants fail to provide a written description which teaches how to make and use same in a process for preparing a labeling reactant of formula (I). The essential novelty, the essence of the invention, must be describe in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention.

A broad claim requires a correlatively broad and sufficient disclosure to support it. Presently, the examples in the instant specification are limited to the preparation of compounds 1-38, introduction of primary amino groups to the oligonucleotide structure

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with the aid of compound 3, introduction of lanthanide(III) chelates to the oligonucleotide structure with the aid of compound 8, and the introduction of a lanthanide(III) chelate to the oligonucleotide structure with the aid of compound 38. Examples and description should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula. A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound. The process is considered to be incomplete wherein applicants set forth the preparation of compounds wherein various moieties are left undefined in full, clear and exact terms.

The written description requirement for a claimed genus may be satisfied through sufficient description of an adequate representation of species by functional characteristics sufficient to show the applicant was in possession of the claimed genus. An adequate representation of species requires that the species which are expressly described and recognized in the art as representative of the entire genus. What constitutes a "representative number" is an inverse function of the predictability in the art in question. As such, there is not seen any data or correlative prior art evidence which supports applicant's claim that at the time of filing, the application was in possession of an adequate, representative number of compounds of formula (I) as broadly claimed.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Regarding claim 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

9. In claim 1, the parenthetical phrases " $-(C\equiv C-)$ ", " $-(O-)$ ", " $-(S-)$ ", " $-(CO-NH-, -NH-CO-, -CO-NR'-$ and $-NR'-CO-)$ ", " $-(CO-)$ ", " $-(COO-$ and $-OOC-)$ ", " $-(S-S-)$ ", " $-(N=N-)$ ", and " $-(N-R')$ " renders the claim indefinite because it is unclear whether the limitation(s) enclosed in parentheses are part of the claimed invention. See MPEP § 2173.05(d).

10. Regarding claims 2-3 and 6-8, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-2, 4-5, and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kwiatkowski et al. Nucleic Acids Research, 1994, Vol. 22, pages 2604-2611 (Kwiatkowski).

Kwiatkowski discloses modified nucleoside phosphoramidites within the scope of instantly claimed formula (I) as instantly claimed. See compounds 8 and 9 (page 2607, Scheme 1).

13. Claims 1, 3, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigmund et al. Nucleosides & Nucleotides, 1997, Vol. 16, pages 685-696 (Sigmund).

Sigmund discloses nucleoside compounds within the scope of instantly claimed formula (I) as instantly claimed. See compound 13 (page 687).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 1-5 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwiatkowski et al. Nucleic Acids Research, 1994, Vol. 22, pages 2604-2611 (Kwiatkowski) in combination with Sigmund et al. Nucleosides & Nucleotides, 1997, Vol. 16, pages 685-696 (Sigmund) and Nardone et al. WO 99/64431 (Nardone).

Claims 1-5 and 8-11 are drawn to a labeling reactant of formula (I).

Kwiatkowski teaches modified nucleoside phosphoramidites within the scope of instantly claimed formula (I) as instantly claimed. See compounds 8 and 9 (page 2607, Scheme 1).

Kwiatkowski differs from the instantly claimed invention in that Kwiatkowski does not teach compounds wherein G is an organic dye or a bivalent aromatic structure. However, these deficiencies would have been obvious in view of the teachings of Sigmund and Nardone.

Sigmund teaches nucleoside compounds within the scope of instantly claimed formula (I) as instantly claimed. See compound 13 wherein G is an organic dye (fluorescein) (page 687). Nardone teaches nucleoside compounds within the scope of

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instantly claimed formula (I) as instantly claimed. See compound (XIV) wherein G is a bivalent aromatic structure (page 26, Example 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the fluorophore taught by Kwiatkowski with the fluorophore taught by Sigmund or Nardone. The selection of a known material based on its suitability for its intended use is *prima facie* obvious. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In the instant case, the said fluorophores are seen to serve the same function. One would have been motivated to do so in order to aid in the detection of trace amounts of nucleic acid from pathogenic bacteria and viruses

Conclusions

18. Claims 1-13 are pending. Claims 1-11 are rejected. Claims 12-13 are withdrawn from consideration as being drawn to a nonelected invention. No claims are allowed.


Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 10:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
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